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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/435,576 | 11/08/1999 | CHIH-MING CHEN | 300.1003 | 5401 |

23280 7590 06/18/2002

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| EXAMINER |
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WILLIAMSON, MICHAEL A

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 06/18/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/435,576

Applicant(s)

CHEN ET AL.

Examiner

Michael A. Williamson

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 08 January 2002.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-75 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4&11.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

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DETAILED ACTION

Pending Claims

The pending claims in the instant application are 1 -75. The independent claims are 1, 48, 51, 58, 62, 70-72 and 74.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-75 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a controlled release oral solid dosage form comprising a core of an alkyl ester of a hydroxy substituted naphthalene compound, a pharmaceutically acceptable , water swellable polymer and an osmotic agent and an outer coating layer which completely covers the core comprising a pH sensitive coating agent and a water insoluble polymer used at a weight ratio of about 0.1:1 to 0.75:1 at a combined coating weight of 0.5-5% by weight, does not reasonably provide enablement for a controlled release oral solid dosage formulation without the recited limitations regarding a core and an outer coating having the weight ratio and combined coating weight has been maintained for reasons of record in paper number 2, paragraph 2.

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Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberts et al. (U.S. Patent 4,997,658).

Alberts et al. discloses an alkyl ester of a hydroxy substituted naphthalene derivatives, including lovastatin, which is a medicament used in lowering the plasma cholesterol level in a subject by time-controlled administration (see entire document). Alberts et al. does not disclose materials that are similar or the same as those of used in the instant claimed invention.

Oshlack et al. discloses structural components as well as compositions used to overcoat active agent including pharmaceuticals (see Abstract and entire document). The advantage of the overcoat is to protect from the environment. Therefore, it would have been obvious to one of ordinary skill in the art to use the coating compositions disclosed by Oshlack et al. in the invention of Alberts et al. to obtain an active

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ingredient that is protected from the environment to provide stability in the absence of a factual showing to the contrary or a showing of unexpected result.

4. The rejection of claims 1-75 under 35 U.S.C. 103(a) as being unpatentable over Monaghan et al. (U.S. Patent 4,231,938) in view of Oshlack et al. (U.S. Patent 5,324,351 or 5,472,712) has been withdrawn in view of Applicant's arguments.

Double Patenting

5. The rejection of claims 1-75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,916,595 has been withdrawn in view of Applicant's submission of a Terminal Disclaimer.

Response to Arguments

6. Applicant's arguments filed March 9, 2001 have been fully considered but they are not persuasive.

Applicant argues that the instant claimed invention is enabled because a number of technologies are disclosed and supported by the specification (see page 2,

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Enablement continued to page 4). Applicant is claiming an article in claims 1-47 using functional language. Applicant has named a limited number of materials that meet said limitations. It is therefore the Examiner's position that the instant claimed invention is limited to the as is determined by the materials used since it is not what additional materials meet the limitation of the functional language used.

7.

Crystal Mall 1 Facsimile Center

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

8. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.



Michael A. Williamson
Patent Examiner
Group 1610

Williamson020617
June 17, 2002